

## **REMARKS**

### **The Amendments**

Claim 1 is amended to specify that the active agent of the claimed compositions “consists of” the a *(I)* dopamine D2-receptor agonist and *(II)* an anti-cholinergic agent. Thus, the compositions exclude other active agents/ingredients. Claim 1 is further amended to address the 35 U.S.C. §112 rejection, as discussed below. The claims are otherwise amended to correct obvious informalities.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Restriction Requirement**

In response to the Final action on the restriction requirement, applicants have filed concurrently a Petition to Withdraw the restriction requirement.

### **The Rejection under 35 U.S.C. §112, first paragraph**

The rejection of claims 1-4, 6-10, 20-24, 26-31 and 33-34 under 35 U.S.C. §112, first paragraph, is believed to be rendered moot by the above amendment to claim 1. The recitation “the group consisting of tiotropium, a pharmaceutically acceptable salt thereof, an isomer thereof, an isotope thereof, a polymorph thereof, a hydrate thereof and a solvate thereof,” clearly sets forth the possible alternatives in proper Markush terms. Although applicants do not believe Markush terms are required to be in singular form, they have been amended in this manner to expedite prosecution.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 1, 2-4, 6-10, 20-22, 23-24, 26-31 and 33-34 under 35 U.S.C. §103, as being obvious over Bannerjee (U.S. Pub. No. 2002/0151598), is respectfully traversed.

Initially, applicants urge that the PTO has not met its burden of establishing that Bannerjee is available prior art to the instant claimed invention. The current record only establishes an effective US filing date (and thus 35 U.S.C. §102(e) date) of the Bannerjee reference as of the filing date of the parent application, i.e., June 22, 2001. Applicants claim an effective filing date through their first provisional application filing of May 25, 2001. This is prior to the 102(e) effective date of Bannerjee established on the record. Bannerjee does also claim priority to a US provisional application filed April 17, 2001. However, the record does not establish that that provisional filing supports the subject matter relied upon in making the rejection. Thus, a 102(e) effective date back to that provisional date of Bannerjee is not proven on the record. In the absence of such proof, Bannerjee is not established as prior art and the rejection based thereon should be withdrawn.

In any event, applicants urge that the disclosure of Bannerjee in the published application does not render the currently claimed invention obvious to one of ordinary skill in the art.

Bannerjee discloses compositions for treatment of bronchorestrictive disorders in a pharmacologically stable fluid form. The compositions are required to contain a bronchodilating agent selected from the list provided in para. 0008, pages 1-2. All of these compounds are  $\beta_2$ -adrenoreceptor agonists. Particularly, the compositions contain formoterol; see, e.g., para. 0002, page 1. Bannerjee discloses that optionally other agents can be administered together with the  $\beta_2$ -adrenoreceptor agonist and exemplifies the combination

with a dopamine receptor agonist, a steroid and an anticholinergic agent (para. 0076). The list of examples of dopamine receptor agonists includes pramipexole and the list of examples of anticholinergics includes tiotropium bromide.

Although Bannerjee suggests the option of including the additional actives of a dopamine receptor agonist and an anticholinergic agent in its compositions, it only suggests using these components together with the  $\beta_2$ -adrenoreceptor agonist component. The  $\beta_2$ -adrenoreceptor agonist component is a necessary active agent in the Bannerjee compositions. Thus, Bannerjee does not suggest compositions wherein “the active agent consists of (I) a dopamine D2-receptor agonist, and (II) an anti-cholinergic agent” as recited in instant claim 1. There would be no motivation or other reason for one of ordinary skill in the art to modify the teachings of Bannerjee to provide a composition absent the  $\beta_2$ -adrenoreceptor agonist component. To the contrary, modification of Bannerjee in this manner would be directly contrary to the teachings and objectives of the reference since the inclusion of the  $\beta_2$ -adrenoreceptor agonist is a main characterizing feature of the Bannerjee invention and Bannerjee absolutely requires inclusion of the  $\beta_2$ -adrenoreceptor agonist component.

Accordingly, applicants urge that Bannerjee, considered as a whole, fails to render the claimed invention obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

No fee is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: 1/1346

Date: May 14, 2008

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